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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/484,337	06/07/1995	MICHAEL T. BREWER	65850-105-4.	4386

20306 7590 12/20/2001

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CHICAGO, IL 60606

EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

29

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.



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DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/12/99, 12/2/99, 12/13/99

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 76-82 is/are pending in the application.

Of the above, claim(s) 78, 79 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 76, 77, 80-82 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 76-82 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 27

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

**Part III: Detailed Office Action**

**Notice:** Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Lorraine Spector in Group Art Unit 1647.

5 Since this application is eligible for the transitional procedure of 37 C.F.R. § 1.129(a), and the fee set forth in 37 C.F.R. § 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 C.F.R. § 1.129(a). Applicant's first submission after final filed on 8/12/99 has been entered.

10 All previously pending claims have been canceled. Newly submitted claim 76-82 are pending. Claims 78-79 are withdrawn from consideration as being drawn to a non-elected invention, election having been made in paper number 11.

Claims 76, 77 and 80-82 are under consideration.

**Formal Matters:**

15 In view of the papers filed 12/12/01, the inventorship in this nonprovisional application has been changed by the deletion of Karin Hale, Charles Squires, James Vannice, Michael King, and Rebecca Vanderslice.

✓ The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

**Double Patenting Rejections:**

25 A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

30 A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal

disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 80-82 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-9 of prior U.S. Patent No. 6,143,866. This is a double patenting rejection.

5 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

10 A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

15 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

20 Claims 76 and 77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No. 6,143,866. Although the conflicting claims are not identical, they are not patentably distinct from each other because one would necessarily have to have in hand the isolated nucleic acid of claim 76 to make the vector of claim 7 of the patent, and claim 77 is one of only four species of claim 7 of the patent. Thus, although the claims vary in scope, the currently claimed species are claimed by and therefore obvious over the patented claims.

25 **Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

30 Claims 76, 77 and ~~80-82~~ are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 Claim 76 is indefinite because the amino acid sequence encoded by the nucleic acid sequence shown in Figure 20 does not have a cysteine residue at residue 14 or residue 105, therefore the nucleotide sequence as shown in Figure 20 cannot encode such.

✓ In addition, as all cells are either eukaryote or prokaryote, claim 82 is not further limiting of claim 81.

The remaining claims are indefinite for depending from an indefinite claim.

10 **Rejections Over Prior Art:**

*Priority determination:* The Examiner has determined that the claimed subject matter merits priority to application serial number 08/375242, filed 1/19/95. While application number 07/479661 filed 2/7/90, has the sequence of Figure 20, it does not express the concept of cysteine substitutions at positions 14 or 105 of the encoded protein, so priority to that application is not merited.

15 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

25 Claims 76 and 80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallach et al., EP 0 308 378, and under 35 U.S.C. §(e) as being anticipated by Wallach et al., U.S. Patent Number 5,695,953.

Both Wallach et al. references are previously of record. Both teach nucleic acids encoding the protein of Figure 19 of this application, i.e. the nucleic acid encoding the protein encoded by the

nucleic acid of Figure 20 of this application. Both teach vectors, host cells, and recombinant production of protein. See the claims of the /953 patent, for example. Due to the indefiniteness of claim 76, the claims encompass wild-type sequences, that is, sequences which do not have cysteine substitutions at positions 14 or 105. Accordingly, the claims are anticipated by the prior art.

**Advisory Information:**

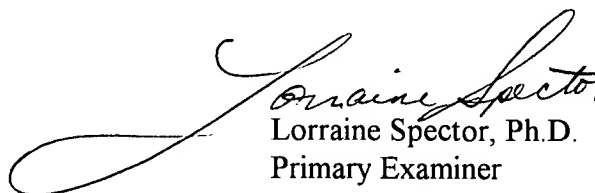
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

  
Lorraine Spector, Ph.D.  
Primary Examiner

LMS  
08/484337.s1  
12/17/01